
NATIONAL INSTITUTE ON DRUG ABUSE (NIDA)

The mission of the NIDA is to lead the nation in bringing the power of science to bear on drug abuse and addiction, through support and conduct of research across a broad range of disciplines and by ensuring rapid and effective dissemination and use of research results to improve prevention, treatment, and policy. For additional information about areas of interest to the NIDA, please visit our home page at <http://www.nida.nih.gov/>.

Division of Treatment Research and Development

The NIDA DTR&D supports research aimed at the development and testing of pharmacological and behavioral treatments for drug abuse and addiction. This includes the identification, evaluation, development, approvability, and efficacy testing of new and improved pharmacotherapeutic agents, as well as the testing of marketed medications, and of behavioral treatments used alone or integrated with medications. The DTR&D also advances a human neuroscience research and training program focused on understanding the neurobiological substrates of drug abuse and addiction processes.

A. *Chemistry and Pharmaceutics Branch (CPB)*. The CPB supports research in the design (including molecular modeling and structure-activity relationship studies) and synthesis of novel compounds, formulation development, bioanalytical methods development, and pharmacokinetics/pharmacodynamics aimed at the discovery and development of new medications for treating drug addiction. (NIDA-CPB). Areas that may be of interest to small businesses include, but are not limited to:

1. ***Research Related to the Design and Development of New Compounds and Improved Drug Products (Drug Delivery) for the Treatment of Drug Addiction***

- a. Synthesis of new chemical compounds that would have potential as treatment agents for the medical management of stimulant (e.g., cocaine, methamphetamine, or nicotine) addiction. Consideration should be given to the design of partial agonists or pure antagonists that diminish the reinforcing effects of stimulants, as well as full agonists that could function to normalize physiological activity following discontinuation of stimulant use. Although typically these types of compounds are designed to affect dopaminergic and/or serotonergic activity, compounds acting through other mechanisms are also of interest.
- b. The development of combinatorial libraries for discovery of drug addiction pharmacotherapies.

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- c. Synthesis of new chemical compounds with potential for the treatment of opioid dependence and/or craving. Compounds which may prevent relapse to opiate use following a period of drug abstinence are of special interest.

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- d. Synthesis of new treatment compounds with minimal transplacental (or other) properties to minimize prenatal effects on the fetuses of pregnant addicts.

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- e. Development of new approaches for the administration of potential addiction treatment drugs with poor bioavailability, such as dynorphin and other opioid peptides.
- f. Development of controlled release dosage forms for addiction treatment medications in order to

maintain therapeutic drug levels for extended periods of time to alleviate compliance problems associated with addiction treatment.

- g. Development of new approaches or improved dosage forms for the administration of addiction treatment drugs to infants suffering adverse effects due to prenatal drug exposure (e.g., opiate withdrawal symptoms).

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- B. *Medications Discovery and Toxicology Branch (MDTB)*. The MDTB supports research on the development of preclinical behavioral models (e.g., of craving, drug-seeking behavior, dependence, or relapse), biochemical assays, gene expressional assays and electrophysiological methods to identify and characterize new medications to treat substance abuse, as well as pharmacological screening of novel compounds to identify potential drug abuse medications. The Branch also supports research on toxicity studies of potential medications for the treatment of substance abuse, and interactions of potential treatment medications with abused substances. Areas that may be of interest to small businesses include, but are not limited to:

1. ***Development of New Methods for Discovery of Medications Useful in Treating Drug Addiction.*** Of special interest would be the development of new animal models of addiction, incorporating established drug self-administration techniques that show increased relevance to the clinical setting. Development of relevant biochemical or electrophysiological screening methods is also encouraged.

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2. ***Development of Methods to Detect Adverse Cardiovascular Interactions Between Cocaine and Potential Cocaine Dependence Treatment Medications.*** The development and

validation of in vitro and/or in vivo bioassay methods for the identification of adverse cardiovascular properties of potential cocaine addiction treatment medications are of special interest to the NIDA Treatment Research and Development Division. Since it is reasonable to believe that patients receiving cocaine dependence treatment medications may occasionally self-administer large quantities of cocaine, the bioassay procedures should be applicable not only to the study of the medication alone, but also to the study of cocaine/medication combinations.

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- C. *Behavioral Treatment Development Branch (BTDB)*. The BTDB supports research on behavioral treatments and combined behavioral and pharmacological treatments for drug abuse and dependence. Behavioral treatments include psychotherapies, behavior therapies, family therapies, group therapies, counseling strategies, rehabilitative techniques, brief behavioral interventions, therapeutic community treatments, and other psychosocial treatments. Research on these treatments may be carried out in any setting, including both academic and community or "real-world" settings. Areas that may be of interest to small businesses include, but are not limited to:

1. ***Behavioral Strategies for Increasing Compliance in Taking Treatment Medication.*** Research to develop and to evaluate strategies to induce recovering addicts to take medication for a prolonged time, especially antagonists such as Naltrexone; to induce HIV infected drug users to comply with medical treatments (HAART) in drug abuse treatment settings; or to adapt existing behavioral strategies to increase patient compliance and cooperation in long-term treatment for drug abuse or for diseases associated with drug abuse such as tuberculosis or hepatitis. An important consideration should be cost and practicality of use in actual clinical practice or in an aftercare program.

The product of such research might be a manual, which describes the behavioral strategy, and its implementation by treatment staff or scientific data regarding evaluation.

2. ***Integration of Behavioral Therapies and Pharmacotherapies.***

Development and testing of integrated therapeutic approaches for individuals who abuse various drugs, including methamphetamine, cocaine, nicotine, and opioids; in addition this may include individuals with co-occurring substance abuse and mental disorders, since effective treatment of both disorders may lead to improved treatment outcomes. Integrated behavioral therapies and pharmacotherapies may enhance the efficacy of both types of therapeutic interventions. For instance, the maintenance and detoxification of heroin addicts could perhaps be optimized by the integration of distinctive behavioral therapies devised specifically for opioid agonists, antagonists or partial agonists determined by the heterogeneity of the subgroup of addicts and the pharmacological differences of the medications. Integration of medications and behavioral therapies could possibly enhance compliance with medication regimens, **increase** retention allowing pharmacological effects to occur and prevent relapse to drug abuse and addiction.

3. ***Behavioral Treatment Research for Drug Abuse and Addiction in Primary Care.***

Recent research has shown that physicians and other clinicians often fail to recognize drug abuse or addiction among their primary care patients. In addition, a significant number of these clinicians reported that they did not know how to intervene with their patients if drug abuse or addiction was suspected. Drug abuse related illnesses and morbidity often occur in adults and may have begun in adolescence. However, very little research has been done to develop or test behavioral treatment approaches or combined pharmacological and behavioral treatments for drug abuse and addiction in primary care settings.

The objectives of this initiative are to encourage research on the development and testing of innovative brief behavioral treatment approaches, alone or in combination with pharmacological treatments that may be used in various primary care patient populations and primary care settings. Other goals of this research initiative are to encourage additional research on the development and evaluation of culturally sensitive screening and assessment instruments for use in primary care; and to encourage research on the transportability of efficacious behavioral treatments to primary care settings, as well as research on science-based training approaches for changing primary care clinicians' behaviors regarding their recognition and intervention with drug abusing or addicted patients. While motivational enhancement approaches for some drug abusing populations have been found to be effective, this behavioral approach has not been widely used in primary care.

4. ***Woman and Gender Differences in the Provision of Behavioral Treatments, and HIV/AIDS Risk Reduction Approaches.***

Develop and evaluate specific behavioral treatment approaches targeting drug-addicted women. This may include behavioral therapies, skills training techniques, counseling strategies, and HIV and other infectious disease behavioral risk reduction strategies. This may also include development and testing of training materials that specifically address women and gender differences in drug addiction treatment to promote effective use of research-based treatment approaches. Training materials may involve treatment manuals, training videos, CD and CD ROM technology or other innovative educational strategies for health professionals.

5. ***Transporting Behavioral Treatments to Community Practitioners.***

There is a need for effective methods of transferring behavioral therapies found to be effective in clinical trials to clinical practice. Cognitive-behavioral therapy, operant behavioral therapy, and family

therapy are among the therapies that have been shown to be efficacious in a highly controlled setting and may be helpful treatment approaches in community treatment programs as well. However, community practitioners may have been trained using other approaches and may not have been exposed to these scientifically-based approaches. This is a call for proposals that examine mechanisms to transfer effective research-based drug abuse treatment information and skills-based techniques to practitioners in the community. This may involve the development and testing of training materials and procedures to use in the training of community practitioners to skillfully administer these treatments, including the development of highly innovative technology transfer and communication approaches. Research testing the transportability of empirically supported therapies to the community (Stage 3 research) is an important component of the Behavioral Therapies Development Program.

There is also a need for the development of educational methods to train non-drug abuse health care workers in relating to drug abusers; eliciting medical histories regarding past or present drug abuse; recognition of the signs and symptoms of drug abuse; identification of those at high-risk for HIV and other drug abuse related medical problems such as tuberculosis or hepatitis. Development and validation of a drug abuse screening instrument which can be administered by primary health care providers, and training in administering such an instrument.

6. ***Using Telemedicine to Disseminate Drug Addiction Research Findings to Primary Health Care Providers.***

Telemedicine programs are being used in urban medical centers to rapidly disseminate science-based information on new medical treatments. In addition, approximately one-third of the rural hospitals are now using telemedicine to improve patient care. Health care professionals need science-based information on drug abuse prevention and treatment. Research to develop

and evaluate telemedicine programs to transport science-based information on drug addiction to the primary health care community is encouraged.

7. ***Developing, Evaluating, and Transporting Culturally Sensitive Behavioral Therapies for Racial and Ethnic Minorities.***

Minority populations are disproportionately affected by the consequences of drug abuse. Research to develop and evaluate behavioral treatments that are culturally sensitive and relevant for diverse racial and ethnic minority populations is encouraged. This may include studies of behavioral treatments, alone or in combination with pharmacological treatment, or studies of behavioral strategies for increasing adherence to taking medications. In the development and evaluation of the behavioral treatment, attention needs to be directed at examining medical, social, and cultural factors that may influence adherence to the behavioral treatment approach and treatment outcome. Also, little is known about the transportability of efficacious behavioral treatments for minority populations. Research is needed on how to transport science-based treatments to various racial/ethnic populations.

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8. ***Behavioral Therapy Development.***

Development of new or refinement of existing psychotherapies, behavioral therapies, skills training techniques or drug counseling strategies for the treatment of drug abusers/addicts. Incorporation of HIV risk reduction strategies as an integral component in routine counseling or other behavioral interventions. This would include the development of: therapy manuals, to define exactly what the therapy is and how to administer it optimally; competence and adherence scales, to evaluate the extent to which therapists and counselors are actually providing the therapy intended; process measures, to measure various aspects of the therapeutic interaction; and measures of the integrity and fidelity of

the therapy. The following are of particular interest:

- a. Development of behavioral therapies or components of such therapies that are based on developments and findings from the basic behavioral or cognitive sciences.
- b. Discrete therapy components that address specific problems common among drug addicted individuals and that can be implemented in conjunction with other therapeutic services. For example, an investigator may wish to develop a four session, highly focused, job seeking skills module that can be easily implemented by a wide range of practitioners to effectively increase appropriate job seeking behavior. Other examples include, but are not limited to, modules to engage ambivalent drug dependent individuals in treatment, modules to increase assertiveness in female drug addicts who feel pressured by others to use drugs, or to incorporate effective HIV risk reduction techniques.
- c. Therapies designed specifically to engage and retain individuals in treatment, especially those at high risk for HIV. An example could be a therapy that is: (1) sensitive to the motivational level of the client; (2) is specifically designed to respond to the needs of the individual, whatever his or her motivational level might be; and (3) actively works to increase an individual's desire to remain in treatment.

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9. ***Innovative Technologies for Drug Abuse Treatment, HIV Risk Reduction, and Training Clinicians.*** Relevant research would be directed at the development and evaluation of innovative technologies to treat substance abuse, enhance adherence to medications, and/or reduce risk for HIV infection or transmission. Approaches should be capable of being

readily incorporated at reasonable cost into various treatment settings. Areas of interest include CD-ROM technology, audio delivery devices, photo therapeutic instruments, hand-held computers and virtual reality devices. Also of interest are creative approaches for disseminating science-based behavioral treatments and for training therapists to use scientifically-based treatments for drug abuse and addiction. Such approaches might include internet-based education, virtual reality interactive computer programs, telemedicine, etc.).

10. ***Development of HIV Risk Reduction Interventions.*** Research to develop and evaluate behavioral strategies to reduce HIV risk behaviors in HIV-positive and HIV-negative substance abusing treatment populations. Risk reduction interventions should be specially adapted to patients' age, gender, cultural background and potential cognitive impairments and should address compliance with medical regimens. The product of such research might be educational materials, such as manuals or videotapes that describe the intervention and its implementation by treatment staff.
11. ***Alternative and/or Complementary (A/C) Interventions for Drug Abuse Treatment.*** Research is encouraged on alternative or complementary interventions for drug abuse treatment, A/C interventions could be the sole treatment or could be adjunctive strategies to enhance the therapeutic potency of existing drug abuse treatments. An example of an adjunctive A/C intervention might be where the A/C intervention reduces withdrawal symptoms thus enhancing retention in treatment. Included would be interventions that are commonly used in "real world" treatment settings, but whose therapeutic efficacy has not been scientifically demonstrated. Such interventions include acupuncture, bioelectrical stimulation, exercise, biofeedback, meditation, among others. The product of this research might be a manual or video, which illustrates the

intervention and how it is implemented by treatment staff.

12. ***Modifying Efficacious Behavioral Treatments to be Community Friendly.*** Several behavioral interventions have been found to be efficacious for the treatment of drug addiction. However, there are barriers to implementation of behavioral therapies in community-based settings. Community settings that treat drug addicted individuals are reluctant or unwilling to adopt these interventions for a variety of reasons. Reasons that scientifically-based behavioral treatments are not accepted by community providers could include the excessive cost of implementation, the length of time for administration of treatment, inadequate training available for therapists and counselors, treatments not shown to be generalizable for different patient populations or for polydrug abusing populations, etc. Research aimed at modifying efficacious behavioral treatments to make them more acceptable to community settings is needed. Settings might include, drug abuse treatment facilities, primary care, managed care, and the criminal justice system. Examples of possible studies are those that are designed to reduce the cost of implementation of treatments, reduce the time of administration of treatments, aid in training of therapists, counselors and nurses, adapt individual therapies for group situations, etc.

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13. ***Development of New or Improved Addiction Assessment Measures and Procedures.*** Research directed at the improvement of a currently available measure or the design of a new psychosocial, social or environmental measure appropriate for use in the clinical assessment of substance abusing populations. Special consideration should be given to a specific screening or diagnostic tool, or to a specific measure of treatment readiness, treatment compliance,

service utilization, therapeutic process or drug treatment outcome. The scope of the study might cover the establishment of the instrument's reliability (e.g., inter-rater; test-retest; item-analysis), validity (e.g., discriminant; construct; concurrent; predictive), sensitivity/ specificity, a normative data set for a specific clinical population, a standardized form of administration, different response formats, a specific language version other than English, and/or the instrument's utility in different clinical settings.

14. ***Behavioral Therapies for Pre-Adolescents and Adolescents.*** Behavioral therapies for pre-adolescents and adolescents that incorporate HIV risk reduction counseling as an integral component of the treatment. This includes the development of new, or refinement of existing psychotherapies, behavioral therapies, and counseling (group and or/individual). This also includes the development and testing of manuals as well as other creative, interactive approaches for therapy delivery that may consider different settings for delivery, such as primary care, school-based health programs, juvenile justice settings, etc. Also the behavioral treatments should be culturally and gender sensitive.

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D. ***Clinical Neurobiology Branch (CNB)***

The CNB supports research on the clinical neurobiology of addiction (exploring alterations of the structure and/or function of the human central nervous system following acute or chronic exposure of drugs of abuse), and the neurobiology of development (neurobiological effects of drugs of abuse and addiction during various stages of development and maturation, effects of drug exposure on neurobiological processes, development of methodologies and refinement of techniques used in pediatric neuroimaging). The Branch also supports cognitive neuroscience of drug abuse and addiction,

and the neurobiology of treatment, HIV/AIDS, and human pain and analgesia. Areas that may be of interest to small businesses include, but are not limited to:

1. ***Development of Novel Approaches in Human Neuroscience***

- a. Development of innovative, noninvasive research methods or novel approaches to identify various neurobiological markers of brain alterations in humans induced by acute or chronic exposure drugs of abuse. This may include the identification of neurobiological (including genetic) markers that might be associated with risk for, or resilience to drug abuse and addiction. Of particular interest are noninvasive methods that could be used to determine the effects of drug abuse/addiction treatments on neurobiological systems in an attempt to understand the neurobiological processes underlying therapeutic efficacy.
- b. In recent years, there has been an increase in studies employing functional magnetic resonance imaging (fMRI) to understand brain processes and functional neuronal systems. In particular, these neuroimaging techniques are being used to probe how drugs of abuse alter brain functioning. Consequently, there is a need for the development of stimulus generation hardware to be used in an fMRI scanner that can display stimuli important in drug studies. As the studies of brain function become more sophisticated, task-related assessments of brain activation are increasingly important. Shielded goggles or other types of visual stimulation hardware is necessary for presentation, for example, of neurocognitive tasks, drug-related images for the induction of craving, or other "virtual reality" types of dynamic stimuli important in studies of drug abuse and addiction. Responses to this type of stimulation then could be

correlated with brain measures using neuroimaging techniques. These types of studies will provide new insights into drug-brain-behavior interactions.

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- c. Virtual Reality for the Neurobiological Study of Drug-Brain-Behavior Interactions and Drug Abuse Treatment. Virtual Reality (VR) is an emerging technology proven useful throughout Europe and America in a variety of research-related, therapeutic and instructional settings. By immersing a person's senses in a synthetic world or Virtual Environment (VE) that characterizes VR, a highly flexible and programmable set of stimuli can be used to enhance the standard approaches used in neuropsychological assessment. Collection of real time data and bulk data recording can provide a correlation of a stimulus reference signal with simultaneously collected fMRI scanner and physiological data over time. Unlike most computer access systems that accept only one or two modes of precise and/or discrete input at a time, VR systems have the potential to monitor movement or action from any, or many, neurobiological functions at once. In addition, the multimodal feedback inherent in VR provides a way to vary nonvisual stimulus components (e.g., resistance, temperature, pitch) in a way that is impossible to achieve via standard computer systems. Finally, VR systems provide a bypass for keyboard entry or direct manipulation environments (e.g., pointing instruments like the mouse), by allowing the manipulation of multi-sensory representations of entire environments by natural actions and gestures.

The applications of VR in clinical and basic neurobiological research are uncovering many findings of interest. For example, Ghahramani and Wolpert (1997) used VR to investigate modular decomposition in visuomotor learning with results suggesting that the brain does employ a decomposition strategy during learning. fMRI and VR have been used by Aguirre, Detre, Alsop and D'Esposito (1996) to localize the neural substrates of human topographical spatial learning within the hippocampal system to address conflicting evidence on the regional function of the medial temporal lobes in rodents and primates. Neuronal responses in the motion pathway to natural optic flow stimuli were examined in a macaque monkey (Pekele, Lappe, Bremmer, Thiele, and Hoffmann (1996). There are VR systems that have been specifically designed for the assessment of cognitive functions in individuals with acquired brain injuries. In one instance, VR produced objective clinical evidence of a persisting frontal dysfunction in spite of normal neuropsychological tests traditionally used to tap frontal function.

VE can provide a completely controlled, noninvasive, safe and alternative methodology for a variety of important studies of drug abuse and addiction. For example, VR affords one an avenue to present of a variety of complex, multi-sensory stimuli for neurocognitive tasks or, alternatively, the dynamic stimuli important for producing drug-related images for the induction of craving. VR can also be tested as an alternative to traditional behavioral therapies in the treatment of drug abuse. Responses obtained as a result of the above can then be correlated with brain measures using state-of-the-art neuroimaging techniques. We, therefore, invite studies employing VR, especially to probe

brain processes in drug abuse/addiction combined with neuroimaging methods (contact Ro Nemeth-Coslett), or to be developed or applied as a potential treatment for substance abuse (contact Debra Grossman).

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- d. Development of interactive computer applications for neuropsychological/ neurocognitive assessment to determine functional brain deficits in acute and chronic drug abusers. In addition, a neurobehavioral test battery to assess other neurobehavioral/ neurocognitive deficits resulting from drug abuse/addiction is encouraged. Of particular interest is the development of such assessments for use in children and adolescents exposed to drugs of abuse to better define and understand the effects of early exposure on brain function and development.

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- e. Development of Ligand for Brain Imaging. Development of novel radioligands for PET and SPECT imaging in human brain for molecular targets (e.g., receptors, intracellular messengers, disease-related proteins) of broad interest to the neuroscience and drug abuse research community. The primary application of these radiotracers will be in basic neuroimaging research. Ultimately, these radiotracers may also be used as potential biological markers and surrogate endpoints for translational and clinical research, drug discovery and

development, and clinical trials. The scope of the projects may encompass pilot or clinical feasibility evaluation in pre-clinical studies, model development, or clinical studies. Alternatively, the focus may be on research and development of new technologies for radiotracer development.

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E. Medications Research Grants Branch (MRGB)

The MRGB supports investigations of the use of medications for the treatment of drug abuse and dependence disorders, with the aim of assisting addicts to reduce illicit drug use, become drug free, prolong abstinence, decrease associated psychosocial, medical or legal problems, or survive drug overdose. In general, pharmacotherapies are expected to be added to a platform of appropriate behavioral therapy. The program funds extramural grants in the following areas:

1. Controlled clinical pharmacological studies to assess a compound's potential as a drug abuse/dependence treatment medication.
2. Controlled clinical trials for the assessment of new agents, or new indications for marketed agents, for the treatment of drug abuse or its complications (withdrawal, relapse, overdose).
3. Clinical studies of the pharmacological effects and interactions among experimental addiction medications, the various substances abused by drug-dependent individuals, and other medications used for associated psychiatric and medical conditions.
4. Experimental pharmacotherapy studies aiming to enhance the efficacy of approved, marketed medications for drug abuse/dependence treatment, including methadone, LAAM, buprenorphine, clonidine, nicotine replacements, naltrexone, disulfiram, and bupropion.

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Division of Basic Neuroscience and Behavioral Research (DNBR)

DNBR's basic neuroscience and behavioral research focuses on understanding the mechanisms, characteristics, and processes of drug abuse. Basic behavioral, cognitive, neurobiological, cellular, molecular, chemical, and genetics research aims at characterizing and understanding drug seeking, compulsive behavior, and addictive processes. These research areas necessarily include studies of normal processes.

Using both animal and human studies, basic behavioral research focuses on behavioral and cognitive processes that may or do lead to drug initiation, and the behavioral and cognitive consequences of drug abuse. Neurobiology research focuses on the neural mechanisms and substrates underlying behavioral and cognitive processes and vulnerability factors associated with drug abuse, addiction, sensitization, tolerance, and relapse.

DNBR supports basic chemistry and pharmacological studies focusing on structure/activity relationships, definition, and characterization of systems involved in drug actions, chemical synthesis of new ligands, pharmacokinetics, analytical methods, understanding basic mechanisms of drug action and drug testing.

Computational and theoretical modeling of biological systems and behavioral processes, biomedical computing and/or information science and technology development is supported by DNBR.

- A. Research Related to the Design of New Therapeutic Approaches. Development of new therapeutic approaches based on the application of nanoscale particle formulations for drugs that are either poorly water-soluble or otherwise unstable under physiological conditions, and development of methods for using nanoscale formulations for targeting specific brain sites or to control drug delivery over extended periods of time.

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- B. *Virtual Reality for Treatment of Pain.*
Recent findings (Hoffman et al., 2000, Pain, 85, 305-309) have suggested that Virtual Reality (VR) exposure can reduce reported pain during wound care. Grant proposals are sought to examine the utility of VR technologies in the treatment of various types of pain. Development of treatments for both acute and chronic pain are sought. These treatments can be based in clinical settings or the patient's homes. Phase I testing should establish the feasibility of the use of this technology in the particular population to be tested. Phase I should also produce data that demonstrates that this methodology is effective for the particular type of pain being treated. Phase II should involve larger-scale testing (e.g. more subjects and treatment trials) examining various treatment parameters (e.g. timing of treatment, types of VR environments). The focus of Phase II testing should be the refinement of this treatment for use in pain patients.
- C. *Virtual Reality for the Treatment of Drug Abuse.* Recent findings (Hoffman et al., 2000, Pain, 85, 305-309) have suggested that Virtual Reality (VR) can be a useful clinical tool. In this particular study, VR exposure was used to allow patients to selectively not attend to an otherwise painful procedure. Drug abuse, like pain, is a problem that is strongly impacted by stimuli in the abuser's environment and psychological factors. Thus, it is reasonable to assume that VR may be useful in allowing individuals to ignore drugs cravings, withdrawal symptoms or environmental cues that promote drug abuse. Grant proposals are sought to examine the utility of VR technologies in the treatment of various types of drug abuse. These treatments can be based in clinical settings or the patient's homes. These treatments can be developed to address drug withdrawal, drug craving or on-going drug related behaviors. The development of VR technologies to address abuse of all types of drugs (e.g. cocaine, marijuana, nicotine, alcohol, inhalants) are sought. Phase I testing should establish the feasibility of the use of this technology for

the particular drug problem addressed (e.g. cocaine craving, opioid withdrawal) and should also produce data that demonstrates that this methodology is effective for the particular drug problem. Phase II should involve larger-scale testing (e.g. more subjects and treatment trials) examining various treatment parameters (e.g. timing of treatment, types of VR environments). The focus of Phase II testing should be the refinement of this treatment for use in the treatment of drug abusers.

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- D. *Development of innovative probes and research products/dosage forms for drug abuse/addiction research.* Proposals are solicited for the synthesis of or development of chemicals/drug products/metabolites (agonists, and/or antagonists), or new probes for drug abuse research that can easily be made available to the drug abuse research community at a much reduced cost as compared to current commercial prices. Such compounds could be of any category - narcotics, stimulants, sedatives, or cannabinoids; drug metabolites and drug products.
- Proposals are encouraged that describe methods that:
1. Improve the purity of the compounds;
 2. Alter the delivery characteristics of drug products; and
 3. Propose new chemicals/drug products that are in demand by drug abuse researchers, but are not available currently or are available with great difficulty. The proposal should specify the drug/drug product to be produced.

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- E. *Chemical Libraries for Drug Development.*
The development and biological screening of lead compounds and their combinatorial libraries for use in the area of drug abuse treatment research are encouraged, such as generation of new ligands having opiate receptor selectivity, or ligands with NMDA or serotonergic agonist/antagonist activity

and/or related. These are designed as lead compounds either for drug design or as tools to elucidate mechanisms of action of drug abuse.

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- F. Analytical Techniques. The development of new analytical methods or reagents for use in measuring drugs of abuse and their metabolites in biological systems, such as urine, blood, saliva, sweat, hair, breast milk, brain tissue, and meconium. The methods should be efficient, sensitive, convenient, and cost effective. Modifications and improvements in existing analytical techniques would also be considered, particularly those improving sensitivity and selectivity.

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- G. G Protein Coupled Receptor Monitoring: The National Institute on Drug Abuse supports research on wild type and mutant G protein coupled receptors (GPCRs) such as the opioid, cannabinoid, and orphanin receptors. There is current interest in the cellular dynamics of these receptors, including the processes of activation by various ligands, internalization and recycling, oligomerization, phosphorylation/dephosphorylation, and degradation. In this respect, phase I and combined phase I/II applications are sought in these areas:

1. the development of new fluorescent reagents for conjugation to receptor proteins and their fragments, including quantum dot conjugates and laser-excitable dyes for long visible-near infrared range emission (650-900nm), for use with various technologies, including internal reflectance fluorescence microscopy and confocal microscopy, and protein detection with capillary electrophoresis.
2. the development of expression systems for the production of beta-arrestins and G protein coupled receptor kinases tagged with green fluorescent protein, or its mutants and variants.

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- H. Genetic Studies. The National Institute on Drug Abuse is interested in SBIR proposals that would greatly facilitate the identification of genetic loci that confer vulnerability to substance abuse and addiction. Areas of interest include but are not limited to:

1. Collection and genotyping of human pedigrees and sib-pairs for vulnerability or resistance to drug abuse.
2. Isolation and identification of mutant strains in genetic model systems such as Zebrafish, *Drosophila*, *C. elegans*, mice, and rats that are more vulnerable or resistant to drugs of abuse.
3. Design, development, and marketing of behavioral apparatuses to conduct rapid behavioral throughput screens for identifying genetic vulnerability to addiction in genetic model systems.
4. Development of transgenic models for drug abuse using bacterial artificial or yeast artificial chromosomes.
5. Development of software and databases for candidate genes for drug abuse.
6. Identification and mapping of functional polymorphisms of candidate genes for drug abuse.
7. Placement of candidate genes for drug abuse on biochips.
8. Marker-assisted breeding of congenic mouse and rat strains for mapping quantitative trait loci associated with addiction and drug abuse.
9. Vectors for gene transfer into neurons.

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- I. Drug Testing Development. Development of new, more refined or more practical drug testing methodologies. Studies may focus, but are not limited to the following topics: drug testing methods; drug extraction procedures; methods to control for possible environmental contamination factors; and reference materials. Methodologies with special

application to the workplace, the emergency room, the transportation environment, or other specific settings are welcome. Methodologies with an emphasis upon circumstances for testing such as post-accident testing or readiness for work testing are also encouraged.

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- J. Biotechnology. Development and improvement of techniques for the crystallization of membrane channel proteins usable for structural (microscopic and 2D crystallographic) and functional studies. Applications may focus on various aspects of protein purification, solubilization, and reconstitution in lipid monolayers or bilayers, and crystallization. The goal of the work could be commercialization of a process, reagent, or final product. Application of these techniques to nicotinic acetylcholine receptor subtypes and the NMDA subtype of glutamate receptors would be of particular interest to this Institute.

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- K. Effects of Drugs at the Cellular Level
Development of new imaging techniques, reagents and related hardware and software for dynamic investigations of the effects of drugs of abuse on cellular activities and communications. For example, these techniques might include, but are not limited to, development and utilization of reagents for magnetic resonance microscopy and other MRI methods; development of methodologies applying functional MRI to drug abuse studies; the use of dyes, intrinsic signals, and other optical indicators for studying signal transduction mechanisms, the regulatory control of protein entities (such as phosphorylation), and neuronal excitatory and inhibitory pathways. Areas of interest may include, but are not limited to:
1. Studies using molecular biological techniques to scale-up protein production for investigations aimed at enhancing understanding of the structure, function and regulation of

molecular entities involved in the cellular mechanisms through which abused drugs act.

2. Validated in vitro test systems can reduce the use of animals in screening new compounds that may be of potential benefit in treating drug abuse. Test systems are needed to evaluate activity at receptors or other sites of action, explore mechanism(s) of action, and assess potential toxicity.
3. With the recent success in molecular cloning of various drug abuse relevant receptors, enzymes, and other proteins, researchers will elucidate the molecular mechanism of action of these drugs. Studies to generate strains of transgenic animals carrying a gene of interest are solicited. Of special interest are knockout and tissue-specific knockout animals. These animals can be used to identify gene function, and to study the pharmacological, physiological, and behavioral role of a single gene.

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L. Toxicity Studies

1. Studies on abused drugs and their metabolites to develop methodologies that may be potentially useful in addressing medical emergencies. Such studies might include investigations involving development of pharmacokinetic models, methodologies, and data.
2. Concern remains about the potential acute and chronic neurotoxicity of drugs of abuse. Information is needed about the possible neurotoxicity of pharmacotherapeutic agents with potential for treating drug abuse. Improved methods are needed for identifying, assessing, and quantifying the nature and extent of neurotoxicity. Such studies might include the development or application of quantitative chemical, physiological, or behavioral measurements relating to nervous system injury or methods for quantitative analysis of damage.

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- M. *Development of Diagnostic Tools that are Predictive of Cardiovascular Complications Associated with Crack/Cocaine Use.*
Studies of cardiovascular function are important because of the cardiac complications associated with crack/cocaine use. The mechanisms involved are poorly understood yet, in many cases, life threatening cardiac and vascular events associated with cocaine use have occurred in young healthy individuals. Experimental findings indicate that there may be a sub-population of animals that are more sensitive to cardiotoxic effects of cocaine. Studies are needed to better understand the cardiovascular effects of cocaine in humans.

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- N. *Predisposition to Cardiovascular Complications Associated with Abused Substance(s)* Development of experimental animal models to assess a genetic predisposition or increased sensitivity to cardiac and vascular complications associated with drug use. Such studies might include, but are not limited to, investigations involved with biochemical, physiological and pathological indices of cardiovascular system function.

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- O. *Opioid Peptides* Research and development directed at the medicinal chemistry and molecular pharmacology of opioid peptides, especially in methods development. Areas of interest include but are not limited to:
1. Development of innovative methodologies for the synthesis of opioid peptides to be made available to researchers. Syntheses proposed should be limited to single analogs.
 2. Methods to identify new ligands for opioid receptors and the design of new opioid peptide analogs with therapeutic potential.

3. Development of analytical methodologies for the quantitation of synthetic and endogenous opioid peptides, peptide precursors, and processing enzymes. The innovation may be limited to a part of the method, such as development of a special detector or a sample cell. Methods might include antibody development and development of innovative immunoassays.

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- P. *Dopamine and Serotonin Receptor Ligands.* Both dopamine and serotonin receptors exhibit multiple subtypes. Applications are solicited using chemical combinatorial library techniques to develop ligands having a high degree of selectivity to these receptor subtypes, which can be useful both as pharmacological tools and lead compounds in medicinal chemistry/drug development.

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Office of Science Policy and Communications (OSPC)

A. *Science Policy Branch (SPB)*

1. **Science Education.** In order to improve science education in the area of drug abuse research (e.g., disciplines such as neuroscience, psychology, epidemiology), efforts are needed to develop innovative methods for improving knowledge of and generating interest in science among school children, the general public, and health care providers, including providers involved in drug abuse treatment. These might include but are not limited to:
 - a. Development of methodology to present drug abuse and science information to particular groups, such as kindergarten and elementary school students, African Americans, Hispanics, persons with disabilities and health care providers.

- b. Development of methodology to transfer new knowledge and directions of scientific growth to teachers, curriculum developers and health care providers.
- c. Development of computer based learning systems that allow students to experience the scientific process.
- d. Development of specific materials, activities, or programs that promote science education related to drug abuse, such as exhibits, curriculum materials, coloring books, videos, teacher education workshops, partnership programs with scientists and educators, or workshops for health care providers.

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Division of Epidemiology, Services and Prevention Research (DESPR)

A. Prevention Research Branch (PRB)

The Prevention Research Branch (PRB) supports a program of research in drug abuse and drug related HIV prevention to (1) examine the efficacy and effectiveness of new and innovative theory-based prevention approaches for drug abuse, drug-related HIV/AIDS and other associated health risks, (2) determine the cognitive, social, emotional, biological and behavioral processes that account for effectiveness of approaches, (3) clarify factors related to the effective and efficient provision of prevention services, and (4) develop and test methodologies appropriate for studying these complex aspects of prevention science.

1. **Prevention Research.** Rigorous scientific prevention research is encouraged to study multiple component substance abuse prevention technologies for use at multiple levels of the social environment including: the family, schools, peer groups and organizations, the workplace, health care systems, etc. The purpose of this research is to determine the efficacy

and effectiveness of program materials, training strategies, and other technologies developed to prevent the onset of drug use progression to abuse and addiction and drug-related HIV/AIDS infection. Materials and technologies should entail a comprehensive approach at the universal, selective, and/or indicated levels. Universal prevention interventions target the general population. Selective prevention interventions target subgroups of the population with defined risk factors for substance abuse. Indicated preventive interventions target individuals who are identified as having detectable signs or symptoms foreshadowing drug abuse and addiction and who have not met diagnostic criteria. NIDA encourages the development and testing of innovative prevention intervention technologies that are sensitive and relevant to cultural and gender differences.

- a. Drug abuse prevention methodological research on promising data collection, data storage, data dissemination, and reporting techniques.
- b. Studies that assess reliability and validity of self-report, physiological, and biochemical measures for use in prevention trials in a variety of settings.
- c. Laboratory studies of the mechanisms and effects of persuasive communication (e.g. mass media and print media) on drug related cognition, affect, motivational levels, and behaviors.
- d. Research on the development of risk profiles and assessment methodologies for identification of individuals at-risk for drug abuse.
- e. Design and testing of developmentally appropriate and psychometrically sound diagnostic instruments and observation systems for young children and preadolescents.
- f. Prevention curricula, materials and implementation methods, for prevention service delivery.

- g. Prevention services research on the organization, financing, management, delivery, and utilization of drug abuse prevention programs.
- h. Prevention intervention dissemination technologies, mechanisms, and links that integrate research with practice; specifically the transfer of drug abuse prevention information to practitioners, policy makers, and the public.
- i. Development of community needs assessment tools and services.
- j. Training modules for program implementers of research based substance abuse prevention programs.
- k. Strategies for the integration of proven prevention approaches into existing service delivery systems.
- l. Decomposition of prevention programs to understand components that account for program effectiveness.

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B. Epidemiology Research Branch (ERB)

The Epidemiology Research Branch (ERB) supports an extramural program for epidemiologic research concerning drug abuse which includes (1) incidence and prevalence of drug abuse (in various stages) and related conditions such as HIV/AIDS among general and specific subpopulations, (2) identification and study of resiliency and risk factors associated with drug abuse and related conditions, (3) etiologic studies on the origins and pathways of drug use during various stages of human development, (4) methodological studies designed to measure and improve the accuracy, collection, and reporting of data on drug abuse and related conditions, (5) development of innovative statistical approaches and research designs leading toward improved analysis of drug abuse characteristics, (6) international epidemiologic studies on drug use patterns,

etiologic factors, and related concerns in various national and regional contexts.

1. ***Assessment and Improvement of the Validity of Sensitive Data Collected in Drug Use Surveys.*** The accuracy and validity of self-report of drug use and related behaviors and consequences in the context of epidemiologic surveys is a matter of great concern. Research is needed on various methods of survey data collection that assures more accurate reporting. Techniques such as those based on variations in standard survey protocols, and those based on use of computer-assisted self-interview (CASI) or computer-assisted personal interview (CAPI) methods are encouraged.

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2. ***Instrument Development for Assessing Community Factors that Affect Drug Use and its Consequences.*** Essential to the assessment and analysis of the relationship between contextual/environmental, sociocultural factors, and health is the consideration of community milieu, as the social, physical and economic characteristics of the community context can have both short- and long-term consequences for community members' physical and psychological well-being. In order to elucidate this important connection between community characteristics and behavioral and social consequences of drug use, this announcement is soliciting applications for the development of community diagnostic instruments to facilitate psychometrically sound assessment of such factors. In this context, community is defined in its broadest sense to include social groups comprised of individuals who have formed attachments based on a variety of shared factors, such as, kinship, beliefs and values, race and ethnicity, and territory (e.g. neighborhood). Instruments are needed to provide local specificity on the physical

characteristics as well as the characteristics of important social groups (including the dynamic nature of individuals involvement in such social groups). Such standardized assessments of community characteristics are needed to better understand the full impact of drug use on behavior and to develop targeted interventions to specific community needs.

The consequences of drug use and/or abuse in society take a profound toll on families, schools, and other community institutions and burden the criminal justice, health care, and social welfare systems. Consequences of interest include, but are not limited to, educational and occupational problems (illiteracy, school dropout, unemployment, job absenteeism and turnover), individual criminal activities (violence, vandalism, homicides, sexual abuse, delinquency), and poverty, homelessness, gang activities, drug trafficking and distribution systems, and family disruption and dislocation (family violence, divorce). Yet, research to enhance the understanding of how community factors affect the prevalence and incidence of such outcomes is hindered by a lack of standardized measurement instruments to aid in defining and assessing critical community factors.

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C. Services Research Branch (SRB)

The Services Research Branch (SRB) supports a program of research on the effectiveness of drug abuse treatment with a focus on the quality, cost, access to, and cost-effectiveness of care for drug abuse dependence disorders. Primary research foci include: (a) the effectiveness and cost-benefits and cost-effectiveness of drug abuse treatment, (b) factors affecting treatment access, utilization, and health and behavioral outcomes for defined populations, (c) the effects of organization, financing, and management of services on treatment outcomes, (d) drug abuse service delivery systems and models, such as

continuity of care, stages of change, or service linkage and integration models, and (e) drug abuse treatment services for HIV seropositive patients and for those at risk of infection.

1. **Clinical Staff Management and Development Strategies.** This SBIR initiative will support research to design and test effective models to manage clinical drug abuse treatment staff, to systematically monitor patient problems and clinical issues, and to provide staff development to improve the quality and outcomes of care.

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2. **Drug Abuse Treatment Economic Research** This initiative will support research to design and develop data systems for financial management and economic analysis of treatment programs and larger systems in new healthcare settings and managed care networks. Managerial decision-making requires the implementation of sophisticated data systems to facilitate routine budgeting processes, allocation of resources, performance measurement, and pricing decisions. The focus is on the needs of managers within the organization and managers outside of the organization. Data system development must be based on standard cost behavior and profit analysis. Data systems must be designed with correct cost concepts (accounting and economic) in order to permit cost and pricing decisions to be developed for new treatment technologies and management of on going systems. In research settings, such an initiative is vital for the assessment of new technologies developed for transfer to practice.

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3. **Personnel Selection Technology Research for Drug Abuse Treatment Clinics.** NIDA would be interested in supporting small innovative research that develops and validates generic

selection systems that could be adopted and tailored for use by drug abuse treatment clinics. Like many small businesses, drug abuse treatment clinics have problems attracting and retaining qualified personnel. Also like many small businesses, treatment clinics have limited resources to apply to the recruiting and hiring of new and replacement personnel. Though reliable data are lacking, a great many clinic directors complain of high annual staff turnover rates. This has been attributed anecdotally to poor quality of work life, low wages, low skill levels, incompatibilities with the clinic's treatment philosophy, and the high stress of working with drug abusers. Research has shown that the application of standardized selection methods designed to maximize person-job fit can cost-effectively reduce staff turnover. Systematic methods such as background inventories, protocol-driven interviews, aptitude tests, and credit checks have demonstrated validity for improving person-job fit. Examples of possible projects might include development of easy-to-understand guidance about legal considerations in hiring practices, software that transform job task analysis into selection criteria, interview protocols to standardize applicant screening, tolls to help improve recruitment, and/or self-paced training for hiring officials or interview panels to improve screening reliability.

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4. ***Customer Retention Technology.*** Premature disengagement from drug abuse treatment participation is a common problem and ranges from approximately 30 to 60% based upon the clinic and modality studied. Past research has very frequently attributed dropping out of treatment to participant characteristics (e.g., motivation, addiction severity, co-morbidity) and/or environmental factors (e.g., social pressures, unemployment, homelessness). Seldom has the dropout problem been studied in the

context of customer satisfaction. That is, there is little research looking at the causes of dropping out of treatment attributable to organizational factors (e.g., policies, practices, context) that influence participant withdrawal decisions. Needed are tools and system for assessing and survey drug abuse treatment program participant perceptions and satisfaction levels, summarizing and report participant assessments, interpreting results and adjusting policies and practices to improve satisfaction and participant retention in treatment.

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5. ***Effective Management and Operation of Drug Abuse Treatment Services Delivery.*** The bulk of drug abuse treatment is conducted in small clinical settings with therapeutic staffs of less than a dozen people. Small clinics lack resources to help improve efficiency and effectiveness in both business and therapeutic practices. Areas that may be of interest to small businesses include, but are not limited to:
 - a. Computer-based leader/manager self assessment tools to enable those supervising the delivery of drug abuse treatment services to gain insights about strengths and weaknesses, and to help guide them to improved leadership and management practices.
 - b. Organizational change tools: Handbooks describing step-by-step way to introduce more efficient business practices such as quality management/monitoring, creating empowered work teams, formalized goal setting, improved customer relations, forming organization linkages, and adopting new fiscal and resource management techniques.
 - c. Organizational change tools: Handbooks describing step-by-step ways to introduce more efficient or effective therapeutic practices such as, adding pharmacotherapy in a

previously drug-free clinic, adopting new medical/pharmacotherapy or behavioral interventions, and adopting new approaches to clinical collaboration and/or case management.

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6. ***Web-Based Technologies: Transporting Services Research to Practice.*** This initiative will support the development and testing of the effectiveness of web-based technologies that facilitate transporting drug abuse prevention and treatment services research to practice. Implementation of drug abuse programs in natural settings often is hampered by the lack of needed data on, first, the contents of an intervention, and second, on procedures for implementation – including, agency and/or community organizational structural and financial issues. The application may include, but is not limited to, the development of a web-based/internet-based dynamic library system that would provide current information/findings (targeted research summaries, recruited list serves and other print/electronic communication) on how to effectively and cost-effectively organize, structure and manage prevention and treatment delivery.

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Center on AIDS and Other Medical Consequences of Drug Abuse (CAMCODA)

The Center on AIDS and Other Medical Consequences of Drug Abuse (CAMCODA) develops and administers a national and international program of research on HIV/AIDS and other medical/health, mental health, and developmental consequences of drug abuse. CAMCODA also coordinates research activities, and collaborates with other NIDA components, on issues concerning HIV/AIDS and consequences of drug abuse.

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A. ***Develop Improved Technology for Assessment of Prenatal Drug Exposure and Passive Postnatal Drug Exposure***

1. Develop and refine methods for the detection and quantification of infant exposure to drugs of abuse during pregnancy, including cocaine, marijuana, opiates, and methamphetamines.
2. Develop and refine methods for the detection and quantification of passive exposure to illicit drugs during infancy and childhood.

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B. ***Develop Interactive Database Systems on Human Subjects Issues for Use by Drug Abuse Researchers Studying School-Age Children and Adolescents Drug Use.***

Develop systems to assist investigators in obtaining technical and legal information relevant to involvement of children and adolescents in research on drug abuse. Examples of pertinent situations include tracking long-term health and development of children exposed to drugs during pregnancy, and investigating vulnerability and possible pathways to drug abuse among school-age children and adolescents. These database systems should address issues such as assent and consent, should provide information on variation in laws and guidelines across jurisdictions, should include the capacity for interactive communication on numerous situations potentially facing investigators, and should serve as sources of referral for additional assistance.

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C. ***Develop Improved Methods of Neuroimaging to Assess Structural and Functional Status of the Brains of Children and Adolescents Exposed to Drugs.***

Document the feasibility and accuracy of appropriate and acceptable methods for assessing brain structure and function of

children and adolescents, with special attention to any or all of the following groups: those exposed to drugs during pregnancy, those passively exposed during infancy and childhood, and those actively using illicit substances. Documentation should include attention to such matters as technological difficulties and risks, and standardization issues relevant to testing conditions and image analysis.

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- D. *Develop and Refine Methodologies for Drug Use Measurement Among Adolescents*. Research to develop and refine methodologies for drug use detection and quantification, with special application to the adolescent with HIV infection or at high-risk for HIV infection. This research should address issues of acceptability, reliability, and validity of one or more methods (e.g., interviews, computerized questionnaires, and biological indicators such as saliva or sweat).

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Other Research Topics Within the Mission of the Institute

NIDA encourages applications in other areas of research that may not be listed.

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